



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

June 2013

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male

M1
M2
M3
M4
M5

Female

F1
F2
F3
F4
F5

the data would be shown as:

| Male | | | Female | | |
|-------------|----|----|---------------|----|----|
| M1 | M2 | M3 | F1 | F2 | F3 |
| M4 | M5 | | F4 | F5 | |

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Table of Contents

| Route | Vehicle | Page Number |
|--------|----------|-------------|
| GAVAGE | CORN OIL | 4 |

Version: Jun2013

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Page: 4

Report Date: 06/17/2013

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052000603 | 03/14/07 | 727 | 50(3) | 20(644) | 584.8 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052030401 | N/A | N/A | 0(0) | 0(0) | N/A | TEF evaluation (PCB 118) |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052000603 | 03/15/07 | 729 | 50(5) | 21(637) | 353.0 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052030401 | 03/26/04 | 733 | 52(5) | 21(616) | 383.5 | TEF evaluation (PCB 118) |

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-----------------------|-------------|----------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 27/50 (54%) | | | 40/50 (80%) | 43/52 (83%) | |
| Overall Incidence | Total | 27/50 (54%) | Mean 54% | SD 0% | Total 83/102 (81.37%) | Mean 81.35% | SD 1.9% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 12/50 (24%) | | | 14/50 (28%) | 15/52 (29%) | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total 29/102 (28.43%) | Mean 28.42% | SD 0.6% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 33/50 (66%) | | | 46/50 (92%) | 48/52 (92%) | |
| Overall Incidence | Total | 33/50 (66%) | Mean 66% | SD 0% | Total 94/102 (92.16%) | Mean 92.15% | SD 0.22% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Histiocytic Sarcoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|--|-------|------------|----------|-------|-----------|---------------|------------|----------|
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 3/52 (6%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 3/102 (2.94%) | Mean 2.88% | SD 4.08% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|--|-------|------------|----------|-------|---------------------|------------|----------|
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Complex | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | |
| | | 8/50 (16%) | | | 0/50 (0%) | 3/52 (6%) | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total 3/102 (2.94%) | Mean 2.88% | SD 4.08% |
| | | | | | | | |
| *Brain: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | |
| *Heart: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | | | |
|---|-------|------|------|---------|--------|-------|---------|------------|----------|
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | | 0/50 | (0%) | 0/52 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | 0/52 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | 0/52 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Cholangioma | | | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | 1/52 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 1/102 | (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | 2/50 | (4%) | 0/52 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 2/102 | (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | 2/50 | (4%) | 0/52 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 2/102 | (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 9
 Report Date: 06/17/2013

| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-----------|---------------|---------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/102 (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 3/50 (6%) | 0/52 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 3/102 (2.94%) | Mean 3% | SD 4.24% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|-----------------------|-------------|----------|
| #Mammary Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 3/50 (6%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 5/102 (4.9%) | Mean 4.92% | SD 1.52% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 6/50 (12%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 8/102 (7.84%) | Mean 7.92% | SD 5.77% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroadenoma | | | | | | | |
| | | 1/50 (2%) | | | 29/50 (58%) | 25/52 (48%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 54/102 (52.94%) | Mean 53.04% | SD 7.02% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 30/50 (60%) | 25/52 (48%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 55/102 (53.92%) | Mean 54.04% | SD 8.43% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 32/50 (64%) | 27/52 (52%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 59/102 (57.84%) | Mean 57.96% | SD 8.54% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Myoepithelioma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|---------------|------------|----------|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Oral Mucosa: Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Ovary: Granulosa-Theca Tumor Benign | | | | | | | | |
| | | | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Ovary: Luteoma | | | | | | | | |
| | | | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| *Ovary: Tubulostromal Carcinoma | | | | | | | | |
| | | | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 12
 Report Date: 06/17/2013

| | | Male | | | Female | | |
|---|-------|------------|----------|-------|-----------------------|-------------|----------|
| *Pancreas: | | | | | | | |
| Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 18/50 (36%) | 17/52 (33%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 35/102 (34.31%) | Mean 34.35% | SD 2.34% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 18/50 (36%) | 19/52 (37%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 37/102 (36.27%) | Mean 36.27% | SD 0.38% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/101 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|---|-------|------------|----------|-------|--------|---------------|------------|----------|
| #Skeletal Muscle: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 (0%) | | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | |
| | | 1/50 (2%) | | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | |
| | | 6/50 (12%) | | | | 0/50 (0%) | 1/52 (2%) | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 5/50 (10%) | | | | 1/50 (2%) | 2/52 (4%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 3/102 (2.94%) | Mean 2.92% | SD 1.31% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|---|-------|------------|----------|-------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 7/50 (14%) | | | 2/50 (4%) | 2/52 (4%) | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 4/102 (3.92%) | Mean 3.92% | SD 0.11% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 2/50 (4%) | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 4/50 (8%) | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 15
 Report Date: 06/17/2013

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

| | Male | | | | Female | | | | |
|---|-------|------|---------|------------|--------|-------|---------------|------------|----------|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | 1/52 | (2%) |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | 1/52 | (2%) |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 3/49 | (6%) | | | | | | |
| Overall Incidence | Total | 3/49 | (6.12%) | Mean 6.12% | SD 0% | | | | |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|--------------|------------|-------|-------------|--------------|----------------------|
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 1/46 (2%) | | | 0/47 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/46 (2.17%) | Mean 2.17% | SD 0% | Total | 0/98 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 1/46 (2%) | | | 0/47 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/46 (2.17%) | Mean 2.17% | SD 0% | Total | 0/98 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 13/50 (26%) | | | 11/49 (22%) | 9/51 (18%) | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 20/100 (20%) | Mean 20.05% SD 3.4% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | 2/51 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/100 (2%) | Mean 1.96% SD 2.77% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 13/50 (26%) | | | 11/49 (22%) | 11/51 (22%) | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 22/100 (22%) | Mean 22.01% SD 0.62% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | 1/51 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 0.98% SD 1.39% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|--------|--------------------------------|-------------|-----------|
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) 1/100 (1%) | Mean 0.98% | SD 1.39% |
| | | | | | | | | |
| #Tooth: Odontoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| #Uterus: Carcinoma | | | | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | | |
| #Uterus: Polyp Stromal | | | | | | | | |
| Overall Incidence | | | | | Total | 10/50 (20%) 13/102 (12.75%) | Mean 12.88% | SD 10.06% |
| | | | | | | | | |
| #Uterus: Sarcoma Stromal | | | | | | | | |
| Overall Incidence | | | | | Total | 2/50 (4%) 2/102 (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | | | | | |
| Overall Incidence | | | | | Total | 12/50 (24%) 15/102 (14.71%) | Mean 14.88% | SD 12.89% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Page: 19

Report Date: 06/17/2013

| | Male | | | Female | | |
|--------------------------------|------|-------|---------------|------------|--|----------|
| #Uterus: | | | | | | |
| Schwannoma Malignant | | | | | | |
| | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 0.96% | | SD 1.36% |
| | | | | | | |
| #Vagina: | | | | | | |
| Polyp | | | | | | |
| | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 2/102 (1.96%) | Mean 1.96% | | SD 0.05% |
| | | | | | | |
| #Vagina: | | | | | | |
| Schwannoma Malignant | | | | | | |
| | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 1% | | SD 1.41% |
| | | | | | | |
| #Vagina: | | | | | | |
| Squamous Cell Carcinoma | | | | | | |
| | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 0.96% | | SD 1.36% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied